back a copy of the Form PTO-1449 initialed to acknowledge consideration of the references disclosed therein. The Examiner indicated in the Office Action that the Information Disclosure Statement was not of record, and thus requested that we resubmit the Information Disclosure Statement with the references to obtain consideration of the references. Therefore, Applicants provide copies of the Information Disclosure Statement and date-stamped postcard receipts showing that these documents were originally filed on August 24, 1998. The references were submitted or cited in the parent application. Therefore, copies of the references are not required. However, if the Patent Office cannot locate the references, the Examiner is respectfully requested to contact Applicants' undersigned representative. The Examiner is respectfully requested to consider the references and return a copy of the acknowledged Form PTO-1449 to Applicants' undersigned representative.

Sequence Listing

The Office Action indicates that there is a discrepancy between the sequences contained in the paper copy of the Sequence Listing and the computer readable copy. The discrepancy appears to be caused by Patent Office error. The present application is a divisional of U.S. Patent Application No. 08/480,917, filed June 7, 1995. The present application was filed with a paper copy of the Sequence Listing and a Preliminary Amendment in which a request was made that the computer readable form of the Sequence Listing filed in Application No. 08/480,917, be used in the present application. In response to a Notice to Comply mailed September 30, 1999, a second request was made that the computer readable form of the Sequence Listing filed in Application No. 08/480,917, be used in the present application. It appears, however, that the computer readable form in the present application was transferred from a different application than the one requested. Therefore, in order to avoid unnecessary delay, Applicants submit herewith substitute paper and computer readable copies of the Sequence Listing. A Notice to Comply was not included with the

Office Action; and therefore, Applicants cannot submit a copy herewith as requested in the Office Action.

The attached paper and computer readable copies of the Sequence Listing are submitted in compliance with 37 C.F.R. §§1.821-1.825. The contents of the paper copy and the computer readable copy of the Sequence Listing are the same. No new matter is added.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1, 2 and 5-35 are rejected under 35 U.S.C. §112, second paragraph. Applicants respectfully submit that the above amendments to the claims overcome aspects of the rejection. With regard to other aspects of the rejection, Applicants respectfully traverse the rejection.

With specific reference to the rejection of claims 1, 2, 5, 8, 17, 20 and 24 for containing the phrase "a synthetic or isolated nucleic acid fragment" in the preamble, and then later reciting "or the corresponding RNA sequence," Applicants respectfully traverse the rejection.

Claims 1, 2, 5, 8, 17, 20 and 24 refer to SEQ ID NO: 1, which is identified in the sequence listing as a DNA sequence and contains "T" rather than "U." Therefore, the claims are written to cover (a) nucleotide sequences that are identical or fully complementary to the identified sequence, and (b) nucleotide sequences that are identical or fully complementary to the RNA sequence that corresponds to the identified sequence. Since the corresponding RNA sequence would differ from the DNA sequence, at least with respect to the substitution of uracil for thymine, the claims are written to clearly encompass each of these sequences. Thus, Applicants respectfully submit that claims 1, 2, 5, 8, 17, 20 and 24 are sufficiently clear.

With particular reference to claim 27, the Examiner asserts that the claim is vague and indefinite for failing to recite hybridization conditions. The claims have been amended to

recite that the DNA or RNA is exposed to the probe under such conditions that the probe hybridizes to a particular nucleotide sequence. Applicants respectfully submit that those skilled in the art with the aid of the teachings of the specification and their general knowledge about hybridization would easily conceive hybridization conditions that would allow them to put the invention into practice.

In addition, according to the Office Action, the stated hybridization conditions are inclusive of very low, non-stringent hybridization conditions under which unrelated organisms may be detected. However, claim 27 has been amended to specifically recite that the sample is exposed to the probe under such conditions that the probe hybridizes to an identified nucleotide sequence. One of ordinary skill in the art would routinely be able to select such conditions at which the probes would hybridize to the target sequence based on the size of the probe and the exact purpose of the hybridization reaction.

The claims have been amended to clarify the invention. Based on these amendments and the above remarks, it is respectfully submitted that the §112, second paragraph, rejection should be reconsidered and withdrawn.

Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1, 2 and 5-35 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Applicants respectfully traverse the rejection.

The claims have been amended to further define the invention. The amended claims are fully enabled by the present specification. Independent claims 1, 5, 8 and 27 specifically recite a nucleotide sequence that is identical or fully complementary to a defined sequence. The description in the specification indicating that the defined sequences may be modified does not change the literal scope of the claims. This description in the specification does

however suggest that modifications that would be apparent to one of ordinary skill in the art or modifications that could be determined through routine experimentation should at least be construed to be covered by the claims under the doctrine of equivalents.

In addition, although claims 21-23 encompass percent homology, one of ordinary skill in the art would be able to determine appropriate sequences by merely routine experimentation for various purposes, such as serving as probes or primers.

Thus, Applicants respectfully submit that the present claims are fully enabled. Therefore, Applicants respectfully request that the enablement rejection under §112, first paragraph, be reconsidered and withdrawn.

Claims 1, 2 and 5-35 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse the rejection.

Although the rejection is directed to claims 1, 2 and 5-35, the language of the rejection appears to only address claims 21-23. Only claims 21-23 specifically claim a sequence by reciting its percent homology to a defined sequence. The remaining claims recite specific sequences and fragments.

With reference to claims 21-23, a high degree of homology has been claimed (85%) with respect to a defined sequence. The specification clearly indicates that the inventors contemplated such homologous sequences. See the specification at page 15, lines 15-30. The specification does not specifically indicate where the sequences differ, which is why the claimed sequence is defined in terms of homology to an identified sequence. However, one of ordinary skill in the art certainly understands homology and could easily discern and construct sequences with the claimed level of homology. Such sequences, even though differing from the specifically identified sequences in the specification, can still be utilized by

one of ordinary skill in the art, for example, to function as probes and primers for particular applications.

Under the law relating to 35 U.S.C. §112, the written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention. Kennecott Corp. v. Kyocera International Inc., 5 USPQ2d 1194, 1197 (Fed. Cir. 1987). An invention may be described in different ways and still be the same invention. Id. The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. In re Kaslow, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

The present claims not only have literal support in the specification, but also the specification adequately communicates the necessary information to allow one of ordinary skill in the art to make and use the claimed invention. Thus, Applicants respectfully submit that the present claims are adequately described in the present specification. Therefore, Applicants respectfully request that the written description rejection under §112, first paragraph, be reconsidered and withdrawn.

Rejections Under 35 U.S.C. §102

Claims 5, 6, 8-10, 25, 28-30 and 32 are rejected under 35 U.S.C. §102(b)/(a) by any of Ko et al. and Opperman et al. Claims 5-11, 17, 25, 26 and 28-33 are rejected under 35 U.S.C. §102(e) over any one of Barton or John. Applicants respectfully traverse the rejections.

Claims 5 and 8 have been amended to recite that the probe and primer of the present invention contain no more than 100 nucleotides. The cited art does not teach any nucleic acid having no more than 100 nucleotides that contains five contiguous nucleotides of a sequence that is identical or fully complementary to nucleotides 1232-2207 of SEQ ID NO: 1.

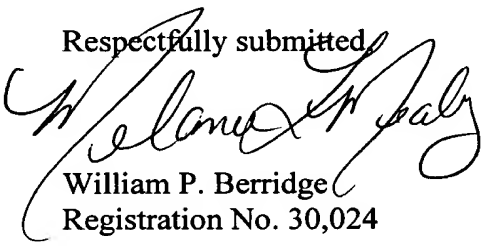
Although the cited art teaches nucleic acids containing segments that correspond to the claimed nucleic acids, all of these nucleic acids have more than 100 nucleotides and the cited art does not teach any shorter segments thereof that correspond to the claimed nucleic acids.

The cited art does not teach each and every feature of claims 5 or 8. The other claims rejected over art depend from one of claims 5 and 8 and are therefore patentable over the cited art for at least the same reasons as claims 5 and 8. Therefore, the art rejections should be reconsidered and withdrawn.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Favorable consideration and prompt allowance are therefore respectfully requested.

Should the Examiner believe that anything further would be necessary in order to place the application in condition for allowance, she is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,



William P. Berridge
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Melanie L. Mealy
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WPB:MLM/ja

Attachments:
- Appendix
- Sequence Listing (paper and computer readable copies)
- Information Disclosure Statement
- PTO stamped postcard receipts

Date: June 21, 2001

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APPENDIX

Changes to Specification:

The Sequence Listing is replaced and moved to the end of the application.

Changes to Claims:

Claims 6, 28 and 30 are canceled.

The following is a marked-up version of the amended claims:

1. (Twice Amended) A synthetic or isolated nucleic acid fragment which comprises a nucleotide sequence that is identical[,] or fully complementary[, or antisense] to a first sequence starting at nucleotide 1232 and ending at nucleotide 1825 of SEQ ID NO: 1 or the corresponding RNA sequence.

2. (Twice Amended) The nucleic acid fragment according to claim 1, wherein said nucleotide sequence is identical[,] or fully complementary[, or antisense] to a second sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence.

5. (Twice Amended) A probe for identifying Trypanosoma cruzi, said probe comprising [a nucleotide sequence that is fully complementary to at least] a segment of at least five contiguous [monomers] nucleotides of a nucleic acid consisting of a nucleotide sequence that is identical[,] or fully complementary[, or antisense] to a sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein said probe contains no more than 100 nucleotides.

8. (Twice Amended) A primer for amplifying a nucleotide sequence, said primer comprising [a nucleotide sequence that is fully complementary to at least] a segment of at least five contiguous [monomers] nucleotides of a nucleic acid consisting of a nucleotide sequence that is identical[,] or fully complementary[, or antisense] to a sequence starting at

nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein said primer contains no more than 100 nucleotides.

9. (Amended) The primer according to claim 8, wherein said [nucleotide sequence] primer comprises [at least five] 5 to 30 nucleotides.

10. (Twice Amended) The primer according to claim 9, wherein said primer comprises a nucleotide sequence [is] selected from the group consisting of SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10 and SEQ ID NO:12.

17. (Twice Amended) The reagent according to claim 11, further comprising at least one primer comprising [a nucleotide sequence that is fully complementary to at least] a segment of at least five contiguous [monomers] nucleotides of a nucleic acid which comprises a nucleotide sequence that is identical[,] or fully complementary[, or antisense] to a first sequence starting at nucleotide 1232 and ending at nucleotide 1825 of SEQ ID NO: 1 or the corresponding RNA sequence.

20. (Twice Amended) The method according to claim 18, wherein before said DNA is exposed to said probe, said DNA is amplified in the presence of an enzymatic system with at least one primer, wherein said primer comprises [a nucleotide sequence that is fully complementary to at least] a segment of at least five contiguous [monomers] nucleotides of a nucleic acid sequence that is identical[,] or fully complementary[, or antisense] to a sequence identified in SEQ ID NO: 1 or the corresponding RNA sequence.

21. (Amended) A synthetic or isolated nucleic acid fragment that comprises a nucleotide sequence having, for [any succession] at least one segment of 30 contiguous [monomers] nucleotides, at least 85% homology with a segment of 30 contiguous [monomers] nucleotides of a sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence.

22. (Amended) The nucleic acid fragment of claim 21, said nucleotide sequence having, for [any succession] at least one segment of 30 contiguous [monomers] nucleotides, at least 85% homology with a segment of 30 contiguous [monomers] nucleotides of the sequence starting at nucleotide 1232 and ending at nucleotide 1825 of SEQ ID NO: 1 or the corresponding RNA sequence.

23. (Amended) The nucleic acid fragment of claim 21, said nucleotide sequence having, for [any succession] at least one segment of 30 contiguous [monomers] nucleotides, at least 85% homology with a segment of 30 contiguous [monomers] nucleotides of the sequence starting at nucleotide 1266 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence.

24. (Amended) The nucleic acid fragment of claim 21, wherein said nucleotide sequence is identical[,] or fully complementary [or antisense] to a second nucleotide sequence starting at nucleotide 1266 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence.

25. (Amended) A probe according to claim 5, wherein said nucleotide sequence is identical[,] or fully complementary [or antisense] to a sequence starting at nucleotide 1232 and ending at nucleotide 1825 of SEQ ID NO: 1 or the corresponding RNA sequence.

26. (Amended) A probe according to claim 5, wherein said nucleotide sequence is identical[,] or fully complementary [or antisense] to a sequence starting at nucleotide 1266 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence.

27. (Amended) A process for detecting and/or identifying Trypanosoma cruzi in a biological sample, comprising:

exposing DNA or RNA from the sample to a probe under such conditions that said probe hybridizes to a nucleotide sequence identical[,] or fully complementary [or

antisense] to a sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence; and

detecting hybridization of the probe to said DNA or RNA to detect and/or identify Trypanosoma cruzi.